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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 04/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,237

Applicant(s)

WEIR ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 7-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 7-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1 and 7-11 of this application.

Specification

2. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states that the various documents "are hereby incorporated by reference in their entirety." Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents. Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents.

3. Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

As set forth In *Ex parte Raible*, 8 USPQ2d 1707, (BPAI, 1998)

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The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree

* * *

We believe that the doctrine of incorporation by reference is of no avail to appellant in this regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the here-claimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon to supplement his disclosure. The purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. In re de Seversky , 474 F.2d 671, 177 USPQ 144 , (CCPA 1973).

4. Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1 and 7-11 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

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To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention”); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) (“the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed”). Thus, an applicant complies with the written-description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” *Lockwood*, 107 F.3d at 1572.

7. For convenience, claims 1, the only independent claim under consideration, is reproduced below.

1. (currently amended) A device for purifying a target nucleic acid from a test sample, the device comprising a plurality of purification units, each purification unit comprising:

(a) a first region comprising a receptacle for receiving the test sample,

(b) a second region comprising an electrophoretic medium comprising at least one immobilized capture probe selected to hybridize to the target nucleic acid in said test sample,

wherein the capture probe is copolymerized to the electrophoretic medium;

(c) a third region comprising a collection chamber for receiving from the electrophoretic medium a molecule other than the target nucleic acid from the test sample from the second region, and

(d) electrodes for generating an electrical field,

the second region comprising a first area interfaceable with the first region opposite from a second area of the second region with the third region,

wherein the electrophoretic medium separates the receptacle from the collection chamber,
and wherein upon application of an electrical current to the electrodes the target nucleic acid in said test sample moves from the receptacle to the electrophoretic medium to form a hybridization complex with the capture probe, and the molecule other than the target nucleic acid from said test sample moves from the receptacle through the electrophoretic medium to the collection chamber.

8. For purposes of examination the claimed device has been interpreted as comprising virtually any nucleic acid sequence that is to serve as a probe. Said probe can be to virtually any target sequence, including nucleic acids found in any life form, including sequences that are as yet unknown. In accordance with claim 11, and by extension claim 1 from which it depends, the device has been interpreted as encompassing an infinite number of different probes and that the

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probes can be of virtually length, including full length sequences of any target sequence, which include but are not limited to genes.

9. A review of the disclosure finds the following examples:

- Example 1, "Purification of a Single DNA Product Complementary to M13mp18 Sequence," pages 23-27;
- Example 2, "Simultaneous Separation of Multiple DNA Sequence Products," pages 27-29;
- Example 3, "Elution of Target from Capture Probe using a Temperature Gradient," pages 29-30; and
- Example 4, "Temperature and Capture Probe Size Dependence of Sequence Elution," page 30.

10. Page 15, lines 9-11, states:

Nucleic acids useful for the probes of the invention include nucleic acids obtained by methods known in the art. These nucleic acids include substantially pure nucleic acids, nucleic acids produced by chemical synthesis and by combinations of biological and chemical methods, and recombinant nucleic acids.

A review of the disclosure, including the above-noted examples, finds but three M13mp18-derived oligonucleotides having been provided, and then they are synthesized with ACRYDITE at the 5' terminus. Clearly, the specification does not reasonably suggest that applicant was in possession of the immense genus of probes encompassed by the claimed device. Further, page 24 of the specification discloses the device comprising a 200- μ l-pipette tip that comprised Hybrigel. The specification teaches that an upper limit for the "plurality of purification units" was but "8 or 12 at a time."

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11. While it may be within the skill of those in the relevant art to find and make probes, the claims currently before the Office are not drawn to a method of making probes or to a method of making the claimed device. Rather, the claims are to the device *per se*, and with the device are the probes. Accordingly, the specification must provide an adequate written description of the full scope of the claimed device and all of its elements so to satisfy the written description requirement of 35 USC 112, first paragraph. While the specification does make reference to various patent and non-patent publications, and goes so far as to assert that these documents have been “incorporated by reference in their entirety,” such documents have been improperly incorporated by reference (*supra*) and as such applicant cannot rely upon these documents for satisfaction of the written description, enablement or best mode requirements of 35 USC 112, first paragraph.

12. The invention also relates to the application of hybridization reaction conditions so to effect separation/purification of the target nucleic acid sequences. As set forth in Carrico, (US Patent 5,200,313) the extent and specificity of hybridization is affected by the following principal conditions:

1. The purity of the nucleic acid preparation.
2. Base compositions of the probe - G-C base pairs will exhibit greater thermal stability than A-T or A-U base pairs. Thus, hybridizations involving higher G-C content will be stable at higher temperatures.
3. Length of homologous base sequences- Any short sequence of bases (e.g., less than 6 bases), has a high degree of probability of being present in many nucleic acids. Thus, little or no

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specificity can be attained in hybridizations involving such short sequences. From a practical standpoint, a homologous probe sequence will often be between 300 and 1000 nucleotides.

4. Ionic strength- The rate of reannealing increases as the ionic strength of the incubation solution increases. Thermal stability of hybrids also increases.

5. Incubation temperature- Optimal reannealing occurs at a temperature about 25 - 30 °C below the melting temperature for a given duplex. Incubation at temperatures significantly below the optimum allows less related base sequences to hybridize.

6. Nucleic acid concentration and incubation time- Normally, to drive the reaction towards hybridization, one of the hybridizable sample nucleic acid or probe nucleic acid will be present in excess, usually 100 fold excess or greater.

7. Denaturing reagents- The presence of hydrogen bond-disrupting agents, such as formaldehyde and urea, increases the stringency of hybridization.

8. Incubation- The longer the incubation time, the more complete will be the hybridization.

9. Volume exclusion agents- The presence of these agents, as exemplified by dextran and dextran sulfate, are thought to increase the effective concentrations of the hybridizing elements thereby increasing the rate of resulting hybridizations.

Further, subjecting the resultant hybridization product to repeated washes or rinses in heated solutions will remove non-hybridized probe. The use of solutions of decreasing ionic strength, and increasing temperature, e.g., 0.1X SSC for 30 minutes at 65 °C, will, with increasing effectiveness, remove non-fully complementary hybridization products.

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13. The failure of the specification to adequately address these aspects raises a reasonable question as to applicant being in possession of a functional device that permits the breadth of purification.

14. Similarly, the claimed device and related kit encompass probes/primers for the detection of any human disease, including all types of cancers. The specification fails to provide an adequate written description of primers and probes that would permit the detection of any and all types of human diseases, including all types of cancers.

15. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

16. For the above reasons, and in the absence of convincing evidence to the contrary, the specification has not been found to set forth an adequate written description of the claimed device and related kit such that it reasonably suggests that applicant was in possession of same at the time of filing.

17. Claims 1 and 7-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described

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in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo*

Biochem Inc., v. Calgene, Inc. (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

18. As presented above, the specification does not reasonably suggest that applicant was in possession of the invention at the time of filing. Accordingly, one cannot enable the use of that which they do yet possess.

19. The state of the art has advanced to where specific difficulties are known to exist. In support of this position, attention is directed to the following.

20. US Patent Application Publication 2003/0133846 teaches:

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Whereas electrophoretic separation of macromolecules is an established technique, the elution of macromolecules from the gel has hitherto represented a difficult and generally non-reproducible procedure.

21. US Patent Application Publication 2002/0090641 teaches:

[0009] According to conventional separating techniques using electrophoresis, the mobility of each of polynucleotides is relative to each other and fluctuates with changes of electrophoresis conditions, and thus identification of an extracted sample solution component is required. In addition, exact separation and purification of a trace quantity of a target polynucleotide is difficult because diffusion in the electrophoresis step can invite contamination of polynucleotides with each other. (Emphasis added)

The instant disclosure, however, is essentially silent as to how these art-recognized problems are to be addressed and overcome. As a result of not enabling the claimed invention, applicant has unfairly shifted the burden of enablement from self to the public. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

“ ‘[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.’ *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) (‘[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.’). ”

“Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that ‘a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.’) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.

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“It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

While the specification has been found to provide some guidance in the four examples found at pages 23-30, such guidance fails to enable the public to overcome art-recognized difficulties and thereby fully enable the claimed invention.

22. In view of the breadth of scope claimed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims are deemed to be non-enabled by the disclosure.

Response to argument

At pages 6-7 of the response received 23 December 2004, hereinafter the response, applicant's representative asserts “the claim term ‘capture probe’ conveys distinguishing information that is readily recognized by one of skill in the art in the context of the claimed invention.”

The above argument has been fully considered and has not been found persuasive for while the term ‘capture probe’ speaks as to how a molecule is to perform, it provides no structure that reasonably suggests that applicant was in possession of this element. The term also does not provide an adequate written description of capture probes such that one would be able to distinguish probes encompassed by the claim from those that are not. While argument is raised

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that “an artisan can readily design a capture probe,” ease or difficulty in making an element does not obviate the need of the specification to provide an adequate written description of the full genus of embodiments encompassed by the claims. It appears that applicant is attempting to satisfy the written description requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

Attention is also directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

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23. At pages 8-14 applicant's representative provides a review of the various *Wands* factors, asserting what is well known and/or within the level of skill of the ordinary artisan. This argument has been fully considered and has not been found persuasive. Attention is directed to MPEP 2145.

Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

24. At page 9 of the response applicant asserts, "The invention is drawn to a device and methods of using the device..." (Emphasis added). It is noted with particularity that only claims 1 and 7-11 are pending- all of which are drawn to a device. No claim is pending that is drawn to a method of using the device.

Claim Rejections - 35 USC § 102

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

26. Claims 1, 7-11, 32, 36, and 39 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The publication of Weir et al., discloses the claimed invention and has been found to teach that it was developed as a result of the actions of four

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individuals, of which three are co-inventors. The instant application names other individuals as inventors, yet are not found on the article, and the article names one Rahul K. Dhanda as a co-author which is not recited as a co-inventor. Consequently, the publication of Weir et al., constitutes the work of another.

Response to argument

Agreement is reached with applicant's representative at page 16 of the response where said representative states in part: "Weir can be considered as a reference with a different inventive entity because it does not name Stephen J. Kron as a co-author..." (Emphasis in the original). Unlike 35 USC § 102(a), which requires the document to have been known to others prior to the filing of the instant application, no such restriction applies against 35 USC § 102(f). Therefore, and in the absence of convincing evidence to the contrary, claims 1 and 7-11 remain rejected under 35 USC § 102(f).

Conclusion

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

28. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
13 April 13, 2005